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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,924	10/31/2000	Hiro Yoshi Hidaka	198323US0PCT	6890

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EXAMINER

TIZIO, STEVEN C

ART UNIT PAPER NUMBER

1627

DATE MAILED: 02/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/647,924

Applicant(s)

HIDAKA ET AL.

Examiner

Steven C Tizio

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☒ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Detailed Action

1. This application is a 371 of PCT/JP98/01712, filed on 4/15/1998.
2. Acknowledgement is made of applicants' claim for priority under PCT/JP98/0712. However, the priority date of 4/15/1998 has not been granted due to the lack of an English translation. This application has the effective filing date of 10/31/2000.
3. The Information Disclosure Statement has been entered on January 10, 2001, and has been fully considered on January 24, 2002.
4. The use of the trademark KWIK SEP (page 7) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.
5. The specification, which is a Japanese translation, has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Art Unit: 1627

6. The abstract of the disclosure is objected to because it contains two paragraphs.

Correction is required. See MPEP § 608.01(b).

7. The title of the invention is not descriptive and unclear. A new title is required that is clearly indicative of the invention to which the claims are directed.

8. Claim 4 is objected to under 37 CFR 1.75(c) as being improper form because a multiple dependent claim depends from another multiple dependent claim. See MPEP § 608.01(n). For compact prosecution claim 4 is treated as dependent on claim 3.

9. Claims 1-4 are pending in this application.

Claim Rejections – 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of the molecular probe containing drug(A)

Art Unit: 1627

to screen a human placenta/ λ Trp1 EX cDNA library, does not reasonably provide enablement for the direct detection of a gene of **any** target protein using **any** type of drug. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims recite a method of detecting the identity of a protein (the gene that codes for that protein) that interacts with a drug of interest. The gene is identified by expressing a library of genes in phage and determining if the drug interacts with the protein expressed on the phage. In the present invention, a particular anti-cancer drug, drug (A), is covalently bound to BSA. As a result, this invention is only enabling with one type of drug, and one type of "antigenic material." In addition, according to page 5 in the specifications, the instant claim 1 is not enabled for living organisms. The disclosure recites an *in vitro* technique utilizing bacteria and phage. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and

- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breath of the claims and the nature of the invention: The claims are drawn to a general method for detecting a gene of a drug-targeted protein in a living organism. The method requires the binding of a drug to an "antigenic substance" and the screening of a cDNA library using the drug-antigenic substance "probe." The only example in the disclosure includes the screening of a drug (A), with little description of drug (A), except that it has "excellent anti-cancer effects." In addition, this example shows an *in vitro* method for detecting genes. The instant claims are drawn to *in vivo* detection methods, and are very broad. The invention is of a general nature.

(3 and 5) The state of the prior art and the level or predictability in the art: Due to the general nature of the invention, there are many variables to consider before using the disclosed invention. Different drugs, detection moieties, and genetic libraries can be utilized depending on the application. It is not possible to predict the scope in which this invention will be used. In the absence of sufficient teachings in the specification, one of ordinary skill in the art would require undue experimentation.

(4 and 8) The level of one of ordinary skill and the quantity of experimentation needed to make or use the invention based on the content of the disclosure: The level of skill

Art Unit: 1627

would be high, most likely at the Ph.D. level. However, the instant disclosure is based on a single drug (drug A) and nowhere in the specification guidance is given as to what type of other drugs (i.e. chemical structure *or* chemical function), can be used in the instant invention. Such persons of ordinary skill in this art, given its unpredictability, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed. Due to the broad nature of the claimed invention and the lack of examples, one skilled in the art would have to use a trial and error method to practice the claimed invention. The disclosure only describes a single example utilizing a non-specific drug (A), a BSA "antigenic substance," a human placenta/ λ Trp1 EX cDNA library, and an *in vitro* screening method. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure, one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants have only provided one example of an *in vitro* gene detection system utilizing drug (A) as the drug, BSA as the "antigenic substance," and a human placenta/ λ Trp1 EX cDNA library as the collection of genes. In addition, the specification

does not enable one skilled in the art to practice the claimed invention in living organisms. Drug (A) is a very vague compound; the disclosure refers to drug (A) as having "excellent anti-cancer effects" (page 6). In addition to the system used by the applicant, there are many combinations of drug, marker compound, and gene libraries (i.e. taxol, luciferase, pancreatic cDNA library, etc.) available. The claimed invention does not give limitations as to the identity of the drug, "antigenic substance," genetic library, and claims an *in vivo* method. As a result, such a claim is very broad and does not give adequate direction to one skilled in the art to utilize the claimed invention.

12. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. There is a step in the gene detection method that is critical or essential to the practice of the invention, but not included in the claim(s) and not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). According to the instant claims, when the drug is administered to the living organism it is not known whether the "antigenic substance" is bound to the drug before or after entering the living organism. Since the gene detection method relies on the drug being attached to an "antigenic substance" to confirm drug-gene product interaction, the disclosure is not enabling for the said method. It is not apparent if the disclosure is enabling for the "antigenic substance" to attach to the drug once the drug enters the living organism or if a drug-"antigenic substance" complex is directly administered to the living organism. In addition, the disclosure does not utilize the

Art Unit: 1627

administration of a drug to a living organism. The disclosure describes an *in vitro* method in which the cDNA library is expressed in phage and the resulting proteins are attached to a nitrocellulose membrane. The membrane is then treated with a probe consisting of a drug-BSA "probe." The disclosure does not describe a gene detection method in which the cDNA library is expressed in a living organism and does not disclose a drug that is administered to the living organism (*in vivo* method).

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) In claim 1, the term "antigenic substance" is a relative term that does not give any information as to the structure or function of the substance. Is it a protein, small organic molecule, or organism? Applicants are requested to clarify.

B) What is meant by "obtained material" in claim 1? There is no mention in the claim or the specifications as to obtaining a particular material. In addition, what is the

Art Unit: 1627

disclosed "material"? Is the "material" the drug, antigenic substance or a combination of both? Applicants are requested to clarify.

C) The term "probe" in claim 1 is indefinite in that the claim does not give a specific description of what the probe consists of. Is the probe the drug, antigenic substance, or a combination of both? Applicants are requested to clarify.

D) What is meant by "the gene of the protein" in claim 1? Does the protein contain a gene or is the gene coding for the protein? Applicants are requested to clarify.

15. Claim 1 recites the limitation "the gene of the protein." There is insufficient antecedent basis for this limitation in the claim.

16. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

a) when the drug is administered to the living organism, is the "antigenic substance" bound to the drug before or after entering the living organism?

17. No claims are allowed.

Art Unit: 1627

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Tizio whose telephone number is (703) 305-1903. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached at (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


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